DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 29, 2015

LED Intellectual Properties, LLC
Mr. Steve Marchese
Chief Executive Officer
16552 Von Karman Avenue
Irvine, California 92606

Re: K142246
Trade/Device Name: LightStim for Acne/ LightStim for Acne Mini
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OLP
Dated: December 23, 2014
Received: December 29, 2014

Dear Mr. Marchese:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142246

Device Name
LightStim for Acne/ LightStim for Acne Mini

Indications for Use *(Describe)*
LightStim for Acne/ LightStim for Acne Mini is an over-the-counter hand-held device intended for the use in the treatment of mild to moderate acne.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary of Safety & Effectiveness

LED Intellectual Properties, LLC.

Device: LightStim for Acne & LightStim for Acne Mini

1. General Information

Submitter: LED Intellectual Properties, LLC
16552 Von Karman Ave.
Irvine, CA 92606

Contact Person: Steve Marchese
Office: (949) 502-4088
Mobile: (949) 394-2427

Date Prepared: August 1, 2014

2. Names and Code

Device Name: LightStim for Acne/LightStim for Acne Mini, model: LS4A/LS4AM

Classification Name: Laser Instrument, Surgical Powered – General and Plastic Surgery – Class II, OLP

Although this device is not a laser and is intended for OTC use, the manufacturer thinks this is the closet applicable classification name.

3. Predicate Devices

Ultra Renew Plus (K132833) and LightStim for Acne Mini (K131461

4. Device Description

LightStim for Acne / LightStim for Acne Mini, model: LS4A/LS4AM is a hand-held device consisting of low intensity light emitting diodes (LED's) that provide illumination which comes in contact with the skin. The device components include LED's of 415nm and 630nm, a hand piece, a printed circuit board, an on/off switch, a resistor, a receiver jack in the hand piece to plug a power supply into and a separate AC to DC (9

volt) power supply. Treatment time is recommended to be three to four minutes and is controlled by the user.

5. Indications for Use / Intended Use

LightStim for Acne/LightStim for Acne Mini, model: LS4A/LS4AM is intended for Over-The-Counter use for the treatment of mild to moderate acne.

6. Performance Data

A usability study was performed on the LightStim for Acne Mini K131461, which is the exact same device but with 415nm Blue LEDs only. This study was conducted with 40 participants. The participants ranged in age from 11 to 61. The results showed that the participants adequately decided whether or not to use the device for their level of acne, and showed that users comprehend risks, warnings, cautions, precautions, and proper use of the device, from the Instruction Manual.

Taking into consideration the (attached) table for substantial equivalence evidencing both predicates being handheld, OTC, utilizing blue light and K132833 also utilizing red light, which poses no new issues of safety or effectiveness as the active wavelength in the treatment of mild to moderate acne is in the blue region of light, thus evidencing the primary objective of acne treatment are common in all of theses devices, and after an analysis of safety, indications, intended uses, performance, features, technological properties and methods of operations. LED Intellectual Properties, LLC believes that LightStim for Acne/LightStim for Acne Mini has shown substantial equivalence to the predicate devices Ultra Renew Plus (K132833) and LightStim for Acne Mini (K131461.

The conclusion drawn by LED Intellectual Properties, LLC is that LightStim for Acne/ LightStim for Acne Mini raise no new issues of safety and are substantially equivalent to the predicate devices.